CLAIMS

What is claimed is:

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- 1. An adenovirus vector comprising an adenovirus gene under transcriptional control of an α fetoprotein transcription regulatory element (AFP-TRE)
- 2. The adenovirus vector of claim 1, wherein the adenovirus gene is essential for viral replication.
- 3. The adenovirus vector of claim 2, wherein the adenovirus gene is an early gene.
- 4. The adenovirus vector of claim 2, wherein the adenovirus gene is a late gene.
- 5. The adenovirus vector of claim 3, wherein the adenovirus early gene is E1A.
- 6. The adenovirus vector of claim 3, wherein the adenovirus early gene is E1B.
- 7. The adenovirus vector of claim 3, wherein the adenovirus early gene is E4.
- 8. The adenovirus vector of claim 1 wherein the adenovirus gene is the adenovirus death protein gene (ADP).
- 9. The adenovirus vector of claim 1, wherein the AFP-TRE comprises an enhancer from an AFP gene.
- 10. The adenovirus vector of claim 9, wherein the enhancer comprises nucleotides from about 1 to about 300 of SEQ ID NO:1.
- 11. The adenovirus vector of claim 9, wherein the AFP-TRE comprises nucleotides from about 300 to about 600 of SEQ ID NO:1.
- 12. The adenovirus vector of claim 9, wherein the AFP-TRE comprises nucleotides from about 1 to about 600 of SEQ ID NO:1.
- 13. The adenovirus vector of claim 1, wherein the AFP-TRE comprises a promoter from a AFP gene.

- 14. The adenovirus vector of claim 13, wherein the AFP-TRE comprises nucleotides from about 600 to about 827 of SEQ ID NO:1.
- 15. The adenovirus vector of claim 1, wherein the AFP-TRE comprises an AFP promoter and an AFP enhancer.
- 16. The adenovirus vector of claim 15, wherein the AFP-TRE comprises SEQ ID NO:1.
- 17. The adenovirus vector of claim 15, wherein the AFF-TRE comprises SEQ ID NO:2.
- 18. A composition comprising an adenovirus of claim 1.
- 19. The composition of claim 18, further comprising a pharmaceutically acceptable excipient.
- 20. The adenovirus vector of claim 1 further comprising at least one additional adenovirus gene under transcriptional control of a second AFP-TRE.
- 21. The adenovirus vector of claim 20, wherein the genes under transcriptional control of AFP-TREs are both early genes.
- 22. The adenovirus vector of claim 21, wherein the genes under transcriptional control of AFP-TREs are E1A and E1B.
- 23. The adenovirus vector of claim 20, further comprising an additional adenovirus gene under transcriptional control of a third AFP-TRE.
- 24. The adenovirus vector of claim 23, wherein the adenovirus genes under transcriptional control are E1A, E1B, and E4.
- 25. A composition comprising an adenovirus of claim 21.
- 26. The composition of claim 25, further comprising a pharmaceutically acceptable excipient.

- 27. A non-naturally occurring adenoviral vector comprising a polynucleotide encoding an adenovirus death protein (ADP) polypeptide.
- 28. The adenoviral vector of claim 27, wherein the ADP polypeptide is a sequence depicted in SEQ ID NO:23.
- 29. The adenoviral vector of claim 27, wherein the ADP polypeotide is SEQ ID NO:23.
- 30. The adenoviral vector of claim 27, wherein the polynycleotide is contained within SEQ ID NO:22.
- 31. The adenoviral vector of claim 27, wherein the polynucleotide is SEQ ID NO:22.
- 32. The adenoviral vector of claim 27, wherein the polynucleotide encoding ADP is under transcriptional control of a cell-specific transcriptional regulatory element.
- 33. The adenoviral vector of claim 32, wherein the cell-specific transcriptional element is prostate-cell specific.
- 34. The adenoviral vector of claim 33, wherein the prostate-cell specific TRE is from prostate specific antigen gene, human kallikrien gene, or probasin gene.
- 35. The adenoviral vector of claim 32, wherein the cell-specific transcriptional element is an AFP-TRE.
- 36. A host cell comprising the adenoviral vector of claim 1.
- 37. A host cell comprising the adenoviral vector of claim 20.
- 38. A host cell comprising the adenoviral vector of claim 24.
- 39. A/host cell comprising the adenoviral vector of claim 27.
- 40. A method of propagating adenovirus specific for cells which allow an AFP-TRE to function, said method comprising combining an adenovirus according

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to claim 1 with cells which allow an AFP-TRE to function, whereby said adenovirus is propagated.

- 41. A method of propagating adenovirus specific for cells which allow an AFP-TRE to function, said method comprising combining an adenovirus according to claim 20 with cells which allow an AFP-TRE to function, whereby said adenovirus is propagated.
- 42. A method for modifying the genotype of a target cell, said method comprising contacting a cell with an adenoviral vector of claim 1 to allow entry of the vector into the cell.
- 43. A method for modifying the genotype of a target cell, said method comprising contacting a cell with an adenoviral vector of claim 20 to allow entry of the vector into the cell.
- 44. A method for conferring selective cytotoxicity on a target cell, said method comprising contacting a cell which allows an AFP-TRE to function with an adenovirus vector of claim 1, whereby the vector enters the cell.
- 45. A method for conferring selective cytotoxicity on a target cell, said method comprising contacting a cell which allows an AFP-TRE to function with an adenovirus vector of claim 20, whereby the vector enters the cell.
- 46. A method of detecting cells which allow an AFP-TRE to function a biological sample comprising the steps of:

contacting a biological sample with an adenovirus vector of claim 1, under conditions suitable for AFP-TRE-mediated gene expression in the cells; and

determining if AFP-TRE mediates gene expression in the biological sample,

wherein AFP-TRE-mediated gene expression indicates the presence of cells which allow an AFP-TRE to function.

47. A method of suppressing tumor growth in an individual having an AFP-expressing tumor, comprising contacting tumor cells with the adenoviral vector

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of claim 2, wherein the adenoviral vector transfects the tumor cells and replicates.

- 48. A method of treating cancer in an individual having an AFP-producing tumor, comprising administering to the individual an effective amount of an adenovirus vector of claim 2.
- 49. An adenovirus comprising an adenoviral vector of claim 1, wherein the adenovirus is complexed with a masking agent.
- 50. The adenovirus of claim 49 wherein the masking agent is polyethyleneglycol (PEG).
- 51. The adenovirus of claim 50, wherein the PEG is of a molecular weight between about 2500 to about 30,000.
- 52. The adenovirus of claim 51, wherein the PEG is of a molecular weight between about 3000 to about 20,000.
- 53. The adenovirus of claim 52 wherein the PEG is of a molecular weight between about 5000 to about 10,000.
- 54. The adenovirus of claim 50, wherein the PEG is covalently attached to the adenovirus.
- 55. The adenovirus of claim 50, wherein the PEG is non-covalently attached to the adenovirus.
- 56. The adenovirus of claim 54, wherein the PEG is covalently attached by using a N-hydroxysuccinimidyl (NHS) active ester.
- 57. The adenovirus of claim 56, wherein the N-hydroxysuccinimidyl (NHS) active ester is selected from the group consisting of succinimidyl succinate, succinimidyl succinamide and succinimidyl propionate.
- 58. The adenovirus of claim 57, wherein the N-hydroxysuccinimidyl (NHS) active ester is succinimidyl succinate.
- 59/ A method of making a masked adenovirus, comprising covalently attaching a masking agent to an adenovirus, wherein the masking agent is has a molecular weight between about 2500 and about 20,000, thereby producing a masked adenovirus.
- 60. The method of claim 59, wherein the masking agent is polyethyleneglycol (PEG).





- 61. An adenovirus complexed with a masking agent.
- 62. The adenovirus of claim 61 wherein the masking agent is polyethyleneglycol (PEG).
- 63. The adenovirus of claim 62, wherein the PEG is of a molecular weight between about 2500 to about 30,000.
- 64. The adenovirus of claim 63, wherein the PEG is of a molecular weight between about 3000 to about 20,000.
- 65. The adenovirus of claim 64, wherein the PEG is of a molecular weight between about 5000 to about 10,000.
- 66. The adenovirus of claim 62, wherein the PEG is covalently attached to the adenovirus.
- 67. The adenovirus of claim 62, wherein the PEG is non-covalently attached to the adenovirus.
- 68. The adenovirus of claim 66, wherein the PEG is covalently attached by using a N-hydroxysuccinimadyl (NHS) active ester.
- 69. The adenovirus of claim 68, wherein the N-hydroxysuccinimidyl (NHS) active ester is selected from the group consisting of succinimidyl succinate, succinimidyl succinamide and succinimidyl propionate.
- 70. The adenovirus of claim 69, wherein the N-hydroxysuccinimidyl (NHS) active ester is succinimidyl succinate.

